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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,978	01/23/2004	Plamen Denchev	205502-9037	9303

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EXAMINER
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HWU, JUNE

ART UNIT	PAPER NUMBER
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1661

MAIL DATE	DELIVERY MODE
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08/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/764,978	<b>Applicant(s)</b> DENCHEV ET AL.	
	<b>Examiner</b> JUNE HWU	<b>Art Unit</b> 1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,5-9,13,14,16-23,27,28,33,34,36-43 and 50-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-9,13,14,16-23,27,28,33,34,36-43 and 50-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

The amendment and declarations filed on May 16, 2008 are acknowledged and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office action.

### ***Status of the Claims***

Claims 2-4, 10-12, 15, 24-26, 29-32, 35, and 44-49 are cancelled and claims 1, 5-9, 13, 14, 16-23, 27, 28, 33-34, 36-43, and 50-60 will be examined on the merits.

The objection under 37 CFR 1.75(c) as being of improper dependent form for further limit the subject matter of a previous claim is withdrawn due to Applicants' remark that lactose is present in some measurable amount up to the percentage claimed.

The rejection under 35 USC 103(a) as being unpatentable under Attree (U.S. Patent No. 6,627,441) in view of Handley et al (U.S. Patent No. 5,491,090) is withdrawn due to Applicants' remark that Attree does not teach lactose can be used in the prematuration media. Moreover, Attree Declaration filed on May 16, 2008 states that Attree (6,627,441) used lactose in the maturation media for osmoticum to increase water stress (paragraph 10). Furthermore, Fowke Declaration filed on May 16, 2008 states that the media used in the induction, maintenance and or prematuration of the instant application contain galactose-containing and lactose (paragraph 11). Attree (6,627,441) does not use galactose-containing sugar and lactose in his media.

The rejection under 35 U.S.C. 103(a) as being unpatentable over Fan et al (U.S. Patent No. 6,689,609) in view of Handley et al is withdrawn due to Applicants' amendment to the claim to immature somatic embryos.

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The rejection under 35 U.S.C. 103(a) as being unpatentable over Coke (U.S. Patent No. 5,534,433) in view of Pullman et al (U.S. Patent No. 6,492,174) is withdrawn due to Applicants' amendment to the claim to immature somatic embryos.

***Claim Rejections - 35 USC § 103***

Claims 1, 5-9, 13, 14, 16-23, 27, 28, 33, 34 and 36-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handley et al (U.S. Patent No. 5,491,090) in view of Schuller et al (Plant Cell, Tissue and Organ Culture 60: 23-31, 2000) and further in view of Find (U.S. Patent No. 6,897,065 B1).

The claims are drawn to a method of reproducing coniferous somatic embryos selected from the family *Pinaceae* including *Pinus taeda* or hybrid thereof and *Picea* comprising growing an immature embryogenic culture derived from an explant on a nutrient medium selected from the group consisting of induction, maintenance, or prematuration media, wherein the nutrient medium comprises of lactose which is more than 1.0% and less than 6.0% of the medium and an additional sugar selected from the group consisting of sucrose, glucose or fructose, wherein the additional sugars are readily metabolized. The nutrient medium further comprises of less auxin, less cytokinin in the prematuration medium, wherein the medium could be gelled or liquid. The induction medium is used to induce embryogenic tissue, the prematuration medium is used to grow and maintain embryogenic culture and the prematuration medium is used to prepare the embryogenic culture for transfer to maturation medium. The prematuration medium further comprises abscisic acid (ABA). The maturation medium does not contain auxin and cytokinin. In addition the embryogenic culture contains early stage embryos. Then the embryos further develop to the cotyledon stage suitable for germination.

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Handley et al teach a method of regenerating *Pinus taeda* in liquid medium, wherein the immature zygotic embryo is culture on initiation (induction) medium that is semi-solid containing a sugar selected from the group consisting of glucose, maltose, sucrose, melezitose and combination thereof (col. 5, lines 62-64, Table II and claim 1), which would include at least two types of sugars (emphasis added). The induction medium contains 0.1 to 5.0 mg of auxin mg/l and 0.1 to 1.0 mg/l of cytokinin (col. 5, lines 59-61). Handley et al further taught that the liquid maintenance medium contains sugar selected from the group consisting of glucose, maltose (6% see Table 2), sucrose (3% see Table 2), melezitose, and combination thereof (col. 6, lines 3-9 and claim 1), which would include at least two types of sugars (emphasis added). The maintenance medium also contains 0.1 to 100 mg/l of auxin and 0.05 to 10 mg/l of cytokinin (col. 6, lines 5-6 and Table II). The sugars were readily metabolized because the embryos further developed. The development (maturation) medium further comprises between 5 to 250 mg/l of ABA (col. 6, lines 17-18) with no auxin and no cytokinin (Table II). At weeks 6, 9 and 12, the embryos were suitable for germination when placed in the development medium (col. 17, lines 48-67). After 12 weeks on the development medium all of the 14 lines developed to stage 2 somatic embryos and in six lines developed to stage 3 somatic embryos (col. 18, lines 1-4). The somatic embryos were allowed to further develop with ABA and the development of cotyledon was noted (col. 19, lines 60 to col. 20, line 30).

Handley et al do not teach that lactose is the primary carbohydrate that is less than 6.0% of the nutrient medium. Handley et al do not teach that the prematuration medium contains less auxin and less cytokinin than the maintenance medium. Nor does Handley teach that the prematuration medium comprises of ABA.

Schuller et al teach the formation and maturation of somatic embryos of *Abies alba*. The proliferation medium was supplemented with sucrose and BA (N<sup>6</sup> benzyladenine, cytokinin) (p.

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24, col. 2, 1<sup>st</sup> full par.). The prematuration media were supplemented with either 58 mM sucrose or 58 mM lactose with or without BA (p. 24, col. 2 and Fig. 1). The maturation media were supplemented with different concentration of lactose and sucrose plus ABA (p. 24, col. 2 and Fig. 1). Schuller noted that the total number of somatic embryos and the number of normal somatic embryos were greater in lactose than with sucrose in the prematuration medium (p. 28, col. 1). Schuller further taught that the lactose containing media produce browning of the embryonal suspensor mass without proliferation; on the other hand, the lactose containing media produced somatic differentiation (p. 28, col. 1). Schuller taught that the combination of lactose and sucrose in the maturation medium stimulated the maturation of the somatic embryos (p. 29, col. 2).

Find taught that suitable carbon sources may be sucrose, maltose, lactose, fructose, glucose, maltotriose, starch, galactose, etc. (col. 4, lines 3-7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of reproducing coniferous somatic embryos, wherein the nutrient medium comprises of a combination of sugars, such as glucose, maltose, sucrose, melezitose in the initiation and maintenance media as taught by Handley et al and to modify that method by substituting one of the sugars with lactose in the initiation or maintenance medium as taught by Find because Find states that lactose is a suitable carbon source. Furthermore, it would have been obvious to try culturing somatic embryos supplemented with lactose with another sugar as taught by Schuller with different culture media, such as initiation, maintenance or prematuration media because lactose and sucrose favors somatic embryos differentiation as taught by Schuller. One would have been motivated to do so given that conifer are important timber crops. Furthermore, one of ordinary skill in the art would have reasonable expectation of success in using lactose and additional sugar in the initiation, maintenance or prematuration

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media because a combination of sugars would aid in the production of cotyledonary stage embryos.

With regard to the amount of lactose in the nutrient medium of more than 1.0% to less than 2.0%, it would have been obvious to one of ordinary skill in the art to use less lactose because Handley et al taught that the sugar content in the initiation and maintenance media is from about 5.0 to 100.0 g/l (Handley col. 10, lines 53-58). Thus, more than 1.0% to less than 2% equivalent well-metabolize carbon source such as lactose is acceptable. One of ordinary skill in the art would have been motivated to use less than 2% lactose in the nutrient medium because 2% is within the limit necessary for the development of embryos.

With regard to the prematuration medium comprising of ABA, it would have been obvious to one of ordinary skill in the art to try to use ABA in the prematuration medium because ABA affected the number of somatic embryos and differentiation of early and late torpedo stages as taught by Schuller et al (p. 28, col. 2). One of ordinary skill in the art would have been motivated to try to use ABA in the prematuration because if it worked in the maturation medium then it may work in the prematuration medium. Furthermore, one of ordinary skill in the art would have reasonable expectation of success in using ABA in the prematuration medium because it would be a choice of experimental design and is considered within the purview of the cited prior art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made as evidenced by the cited references.

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Claims 50-54 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Handley et al (U.S. Patent No. 5,491,090) in view of Fan et al (U.S. Patent No. 6,689,609).

The claims are drawn to a method of reproducing somatic embryo *Pinus taeda* or hybrid thereof comprising growing an immature embryogenic culture derived from an explant on a nutrient medium selected from the group consisting of induction, maintenance or prematuration medium, comprising of between 1.0% and 6.0% lactose for the development of the explant to the cotyledon stage suitable for germination, wherein the maturation medium does not contain auxin or cytokinin.

The teachings of Handley et al are discussed above.

Handley et al do not teach that the nutrient medium comprises of lactose, wherein the lactose is between 1% and 6%.

Fan et al teach a method of nutrimpriming somatic embryos of pines and spruces (Example 4) to produce full-grown plants. The seeds are imbibed in water (initial phase or phase one) then the somatic embryos from the seeds are transferred to nutrimpriming solution for phase two comprising a carbohydrate source such as lactose (col. 10, lines 43-58) at a range of 3-6% (w/v). Phase two is the growth of the zygotic embryos (col. 9, lines 15-17) similar to the maintenance step, wherein the embryos are grown.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of reproducing coniferous somatic embryos, wherein the nutrient medium comprises of a combination of sugars in the initiation and maintenance media as taught by Handley et al and to modify that method by substituting one of the sugars with lactose in the initiation or maintenance medium as taught by Find because Find states that lactose is a suitable carbon source. One of ordinary skill in the art would have been motivated to do so because if lactose was used as a carbon source then it would have been obvious to try lactose



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on the initiation and maintenance media. One of ordinary skill in the art would have been motivated to do so given that *Pinus taeda* is an important timber crop. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Handley and Fan because using lactose in the initiation or maintenance media would be a choice of experimental design and is considered within the purview of the cited prior art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicants' arguments filed on May 16, 2008 have been fully considered but they are not persuasive.

Applicants urge that Fan teaches that the starting material is a mature somatic embryo and that the instant claims are to immature somatic embryo (p. 16 of reply).

This argument is not found persuasive because the rejection is based on a combination of references. Handley et al teaches that the starting material is immature zygotic embryo and this method was combined with Fan who teaches the use of lactose in the nutrient medium.

Applicants urge that Fan does not teach or suggest using medium comprising lactose in the induction, maintenance or prematuration steps of somatic embryogenesis (p. 16 of reply).

This argument is not found persuasive because Fan was combined with Handley et al to show that it would have been obvious to one of ordinary skill in the art to substitute a combination of sugars as taught by Handley with lactose because lactose is another type of carbon source.

Applicants urge that Handley does not cure the deficiency of Fan (p. 16 of reply).

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This is not found persuasive because Fan was combined with Handley to show that lactose can be used in the induction or maintenance medium with good results.

Claims 55-60 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Handley et al in view of Pullman et al (U.S. Patent No. 6,492,174).

The claims are drawn to a method of reproducing somatic embryo by somatic embryogenesis comprising growing an immature embryogenic culture derived from an explant on a nutrient medium selected from the group consisting of maintenance medium and prematuration medium, wherein the nutrient medium comprises between 1.0% and 6.0% of galactose-containing sugar and an additional sugar wherein the coniferous somatic embryo is selected from *Pinus radiata* or hybrid thereof and *Pseudotsuga menziesii* and hybrid thereof, and developing the explant to obtain a cotyledon stage embryo suitable for germination, wherein the maturation medium does not contain auxin or cytokinin.

The teachings of Handley et al are discussed above.

Handley et al do not teach that the nutrient medium comprises of galactose containing sugar.

Pullman et al teach a method of initiating embryogenic cultures of early-midstage (stage 3-5) zygotic embryos (col. 18, lines 1-2) of *Pseudotsuga menziesii* (Douglas fir) (Example 2), and stage 2-4 embryos (col. 19, lines 38-39) of *Pinus radiata* (col. 7, line 44) (Example 3), wherein the explant is induce in liquid media containing between 5 and 70 g/l of maltose (for example 1.5% see Table 47), glucose, fructose, sucrose (for example 1% - 1.5% see Table 3 and 5), galactose, or combination thereof (col. 9, lines 54-58), which would include at least two sugars one being galactose that is between 1% and 6%.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to reproduce coniferous somatic embryos, wherein the nutrient medium contains two

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sugars as taught by Handley et al or Pullman and to modify the sugars by using galactose as the primary sugar as taught by Pullman. Furthermore, Pullman noted that galactose, maltose, glucose, fructose, sucrose and combination thereof are effective carbohydrate energy source (col. 9, lines 54-57). One of ordinary skill in the art would have been motivated to do so given that sugar is necessary for further development of conifer embryos. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of using galactose as the primary sugar and using sucrose or maltose as the secondary sugar, because Pullman states that a combination of sugar could be utilized (col. 9, lines 54-56).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### **Conclusion**

No claims are allowed.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to June Hwu whose telephone number is (571) 272-0977. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private

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JH

/Anne R. Kubelik/

Primary Examiner, Art Unit 1638